

K 091537

**510(K) Summary**

Submitter: Cynosure, Inc.  
5 Carlisle Road  
Westford, MA 01886

Contact: Anthony Burns  
Regulatory Affairs Manager

Date Summary Prepared: May 22, 2009

Device Trade Name: Cynosure Smartlipo Multiwavelength Laser with 1440nm wavelength

Common Name: Medical Laser System

Classification Name: Instrument, surgical, powered, laser  
79-GEX  
21 CFR 878.4810

Equivalent Device: Cynosure Smartlipo Multiwavelength Laser

Device Description: The Cynosure Smartlipo Multiwavelength laser with 1440nm wavelength is a Nd:YAG laser, having a ND:YAG crystal rod as a lasing medium. It is a laser with wavelengths of 1064 nm, 1320 nm, and 1440 nm.

Laser activation is by footswitch. Overall weight of the laser is 285lbs, and the size is 41"x18"x32" (HxWxD).

Electrical requirement is 220 VAC, 20A, 50-60 Hz, single phase.

Intended Use: The SmartLipo Multiwavelength Laser with 1440nm wavelength is intended for the surgical incision, excision, vaporization, ablation, and coagulation of soft tissue. All soft tissue is included, such as skin, cutaneous tissue, subcutaneous tissue, striated and smooth tissue, muscle, cartilage meniscus, mucous membrane, lymph vessels and nodes, organs and glands. The SmartLipo Multiwavelength with 1440nm wavelength is further indicated for laser assisted lipolysis.

Comparison: The Cynosure Smartlipo Multiwavelength Laser with 1440nm wavelength has the identical indications for use, the same principle of operation, and similar laser parameters as the predicate device.

Nonclinical Performance Data: None

Clinical Performance Data: none

Conclusion: The Cynosure Smartlipo Mutliwavelength Laser with 1440nm wavelength is a safe and effective device for the 'indications for use' specified.

Additional Information: none

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Mail Center - WO66-G609  
Silver Spring, MD 20993-0002

Cynosure, Inc.  
% Mr. Anthony Burns  
Regulatory Affairs Manager  
5 Carlisle Road  
Westford, Massachusetts 01886

SEP - 8 2009

Re: K091537

Trade/Device Name: Cynosure Smartlipo Multiwavelength Laser with 1440nm wavelength

Regulation Number: 21 CFR 878.4810

Regulation Name: Laser surgical instrument for use in general and plastic surgery  
and in dermatology

Regulatory Class: Class II

Product Code: GEX

Dated: July 2, 2009

Received: July 6, 2009

Dear Mr. Burns:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

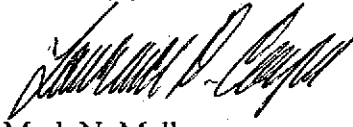
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forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/cdrh/mdr/> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

*FOR*   
Mark N. Melkerson  
Director  
Division of Surgical, Orthopedic  
and Restorative Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

510(k) Number (if known):

K 091537

Device Name: Cynosure Smartlipo Multiwavelength Laser with 1440nm wavelength

Indications For Use:

The Cynosure Smartlipo Multiwavelength Laser with 1440nm wavelength is intended for the surgical incision, excision, vaporization, ablation, and coagulation of soft tissue. Soft tissue includes skin, cutaneous tissue, subcutaneous tissue, striated and smooth tissue, muscle, cartilage meniscus, mucous membrane, lymph vessels and nodes, organs and glands. The Cynosure Smartlipo Multiwavelength Laser with 1440nm wavelength is further indicated for laser assisted lipolysis.

Prescriptive Use X OR  
(Part 21 CFR 801 Subpart D)

Over-The-Counter Use \_\_\_\_\_  
(Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER  
PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

*Michael P. Olsen* *for m.p.*

(Division Sign-Off)

Division of Surgical, Orthopedic,  
and Restorative Devices

510(k) Number

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